



K100715

DEC 23 2010

## 510(k) Summary

### A. Submitter

Aalto Scientific, Ltd.  
1959 Kellogg Ave.  
Carlsbad, CA 92008  
Telephone: (760) 431-7922  
Fax: (760) 431-6824

### B. Contact Person

Dessi Lyakov  
Telephone: (760) 431-7922 Ext. 118  
E-mail: dlyakov@aaltoscientific.com

### C. Date of Summary Preparation

December 23, 2010

### D. Device Identification

Product Trade Name:	Audit™ MicroCV™ Homocysteine Linearity Set
Common Name:	Homocysteine Linearity Set
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJX

### E. Device to Which Substantial Equivalence is Claimed

Product Trade Name:	Liquichek Homocysteine Control Bio-Rad Laboratories, Irvine, California K984071
	Audit MicroCV General Chemistry Linearity Set Aalto Scientific, Ltd., Carlsbad, California K042318



## Description of the Device

The Audit™ MicroCV™ Homocysteine Linearity Set is a human based, liquid, five level set of QC material, with each level containing one analyte: Homocysteine. It is used to confirm the proper calibration, linear operating range, and reportable range of Homocysteine. Level A has concentration near the lower limit level and Level E has concentrations near the upper limit level of instruments. Levels B – D are related by linear dilution of Level A and Level E.

## Statement of Intended Use

The Audit™ MicroCV™ Homocysteine Linearity Set is assayed quality control material consisting of five levels human based serum. Each level contains Homocysteine analyte. The five levels demonstrate a linear relationship to each other for Homocysteine analyte. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Homocysteine. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit™ MicroCV™ Homocysteine Linearity Set should not be used for calibration or standardization of the Homocysteine assay. The Audit™ MicroCV™ Homocysteine Linearity Set is “For In Vitro Diagnostic Use Only”.

## I. Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Audit™ MicroCV™ Homocysteine Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

*Open Vial Stability:* Once a vial has been opened, Homocysteine will be stable for 10 days when stored tightly capped at 2 - 8° C.

*Shelf Life:* Two years, when stored unopened at 2 - 8° C.

*Note:* Real time studies are ongoing to support the shelf life of this product.

## H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit™ MicroCV™ Homocysteine Linearity Set (100715)	Bio-Rad Liquichek Homocysteine Control (K984071)	Audit™ MicroCV™ General Chemistry Linearity Set (K042318)
Intended Use	The Audit™ MicroCV™ Homocysteine Linearity Set is assayed quality control material consisting of five levels human based serum. Each level contains Homocysteine analyte. The five levels demonstrate a linear relationship to each other for Homocysteine analyte. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Homocysteine. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit™ MicroCV™ Homocysteine Linearity Set should not be used for calibration or standardization of the Homocysteine assay. The Audit™ MicroCV™ Homocysteine Linearity Set is "For In Vitro Diagnostic Use Only".	A liquid control for monitoring homocysteine test procedures. This product can be used for methods such as HPLC and automated immunoassay.	Audit™ MicroCV™ General Chemistry Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures. This product may also be used as unassayed quality control material for these same analytes.
Number of Analytes per vial	1	1	31
Number of levels per set	5	2	5
Contents	5 x 1mL	6 x 1mL	5 x 5 mL
Matrix	Human Serum	Human Serum	Human Serum
Type of Analytes	Homocysteine	Homocysteine	Total Protein, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO <sub>2</sub> , Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, LDH, LDL Cholesterol, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid



Form	Liquid	Liquid	Lyophilized
Storage	2 to 8° C for 24 months	-10 to -70° C for 36 months	2 to 8° C for 24 months
Open Bottle Stability	10 days at 2 to 8° C	14 days at 2 to 8° C	7 days at 2 to 8° C

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

AALTO Scientific LTD.  
c/o Ms. Dessi Lyakov  
Manager, Regulatory Affairs  
1959 Kellogg Avenue  
Carlsbad, CA 92008

DEC 23 2010

Re: k100715  
Trade Name: Audit™ MicroCV™ Homocysteine Linearity Set  
Regulation Number: 21 CFR §862.1660  
Regulation Name: Quality control material (assayed and unassayed).  
Regulatory Class: Class I, reserved  
Product Codes: JJX  
Dated: November 22, 2010  
Received: November 23, 2010

Dear Ms. Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

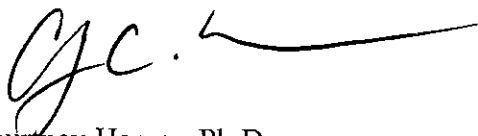
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'GHC', followed by a long horizontal line extending to the right.

Courtney Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

DEC 23 2010

510(k) Number: K100715

Device Name: Audit™ MicroCV™ Homocysteine Linearity Set

### Indications For Use:

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson  
Sign-Off

Office of In Vitro Diagnostic Device  
Regulation and Safety

K 100715